EXHIBIT 3

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA, ex rel. JULIE LONG,

Plaintiffs,

Civil Action No. 16-CV-12182-FDS

v.

JANSSEN BIOTECH, INC.,

Defendant.

<u>DEFENDANT JANSSEN BIOTECH, INC.'S SUPPLEMENTAL OBJECTIONS</u> <u>AND RESPONSES TO PLAINTIFF-RELATOR JULIE LONG'S</u> INTERROGATORY NO. 3, AND AMENDED INTERROGATORY NOS. 8 AND 18

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure, and pursuant to the Order of Judge Saylor (ECF No. 320), Defendant Janssen Biotech, Inc. ("Janssen" or "Defendant") hereby submits these supplemental responses and objections to Plaintiff's Interrogatory No. 3, and Amended Interrogatory Nos. 8 and 18, to identify additional information between February 2016 – February 2020.

Janssen's investigation is ongoing, in light of Judge Saylor's order, issued on September 9, 2022, expanding discovery to February 2020 for documents that (1) mention Relator or her specific claims, and (2) concern the termination or phase-out of any of the specific practices or programs that relator Julie Long participated in, or personally observed, while employed by Janssen, or the potential legality or illegality of any such practice or program. Janssen's Supplemental Objections and Responses to Plaintiff's Interrogatories are based on Janssen's current information and belief as a result of reasonable searches and inquiries. Janssen expressly reserves the right to supplement, amend, and/or correct its responses any time in light of any facts, documents, or other information that may subsequently come to light and/or for any other

appropriate reason. No response or partial response contained herein is to be construed as precluding Janssen from further developing or investigating contentions, facts, documents, or any other matter which is the subject of Plaintiff's Interrogatories, or from modifying or supplementing its responses accordingly.

Janssen's Supplemental Objections and Responses are in addition to and do not waive all objections as to competence, authenticity, relevance, materiality, propriety, privilege, admissibility, and any and all other objections and grounds which would or could require or permit the exclusion of any document or statement therein from evidence. All such objections and grounds are reserved and may be interposed at any time prior to or at the time of trial.

Janssen has constrained its Supplemental Objections and Responses to the Interrogatories below to the scope defined by the Court's order on phased discovery dated December 14, 2020 ("Phased Discovery Order"). Janssen reserves the right to make further objections to any of Plaintiff's Interrogatories should the Court-ordered scope of discovery change. By objecting now, Janssen does not waive any future objections that might be applicable.

GENERAL OBJECTIONS

Janssen makes each of the following general objections, which it incorporates in its responses to each of the Interrogatories:

- 1. Janssen objects to the Interrogatories as untimely under the Court's order dated December 18, 2020, which required written discovery requests to be served by January 22, 2021.
- 2. Janssen further objects to Plaintiff's Interrogatories as in violation of Local Rule 26.1(c) and the Court's order dated December 18, 2020, both of which limit each party to 25 interrogatories. Plaintiff served 18 enumerated interrogatories on January 19, 2021, which Plaintiff amended per Court order on May 14, 2021; 1 enumerated interrogatory on May 13,

2021; and 14 enumerated interrogatories on May 19, 2021; bringing her total number of interrogatories to 33. When factoring in sub-parts of Plaintiff's Interrogatories and Amended Interrogatories, which per the Federal Rules of Civil Procedure should be counted independently, Plaintiff has served, and Defendant has responded to, at least 74 Interrogatories. Fed. R. Civ. P. 33(a)(1) ("Unless otherwise stipulated or ordered by the court, a party may serve on any other party no more than 25 written interrogatories, including all discrete subparts.") (emphasis added); Security Ins. Co. of Hartford v. Trustmark Ins. Co., No. 3:01CV2198 (PCD), 2003 WL 22326563, at *1 (D. Conn. Mar. 7, 2003) ("A subpart is discrete and therefore regarded as a separate interrogatory when it is logically or factually independent of the question posed by the basic interrogatory."); Myers v. U.S. Paint Co., Div. of Grow Grp., 116 F.R.D. 165, 165 (D. Mass. 1987) (The Court can "strike a set of interrogatories in which subparts are utilized merely for the purpose of evading the limit."). When incorporating the subparts to Plaintiff's Definitions and Instructions to her Interrogatories, Plaintiff has served, and Defendant has responded to, over 600 Interrogatories. For ease of reference, Janssen will refer to the interrogatories served by Plaintiff on January 3, 2022, as Plaintiff's Interrogatories 20–22, but Janssen objects that this designation does not accurately reflect the number of Interrogatories served by Plaintiff during the course of this litigation.

3. Janssen's inquiry and research into the subject matter of this litigation, and the items requested and enumerated in the Interrogatories, are ongoing. Janssen intends to conduct further inquiry and investigation. No response or partial response contained herein is to be construed as precluding Janssen from further developing or investigating contentions, facts, documents, or any other matter which is the subject of these Requests, or from modifying or supplementing its responses accordingly.

- 4. Janssen objects to the Interrogatories, Definitions, and Instructions to the extent that they seek to impose obligations or requirements on Janssen which are greater than or different from those imposed by the Federal Rules of Civil Procedure and/or any other applicable law, rule, or regulation.
- 5. Janssen objects to the Interrogatories to the extent they seek documents or information that are neither relevant to the subject matter of this action nor reasonably calculated to lead to the discovery of admissible evidence.
- 6. Janssen objects to the Interrogatories, Definitions, and Instructions, to the extent they are vague, ambiguous, overbroad, or unduly burdensome.
- 7. Janssen objects to the Interrogatories to the extent they seek documents or information not within the control of Janssen. Janssen's Responses are based on information reasonably available to it, and Janssen will respond to these Interrogatories only on its own behalf.
- 8. Janssen objects to the Interrogatories to the extent they seek documents or information subject to and protected from disclosure by the attorney-client privilege, the attorney work product doctrine, and/or any other applicable privilege or protection. Janssen objects to the Interrogatories to the extent they seek to elicit documents or information subject to and protected by the settlement, offer to settle, compromise, offer to compromise, or mediation confidentiality privileges. No written response or production of documents which contains information, opinions, documents, or facts subject to any privilege or protection, or references to information, opinions, documents, or facts subject to any privilege or protection, is to be construed as a waiver of the attorney-client privilege, the attorney work product doctrine, or any other applicable privilege, protection, or doctrine for any purpose. Janssen reserves the right to recall

from discovery any inadvertently produced document that is protected by the attorney-client privilege, the work product immunity, or any other applicable privilege or immunity. If privileged documents are inadvertently produced, Janssen does not waive or intend to waive any privilege pertaining to such documents, or to any other information or documents.

- 9. Janssen objects to the Interrogatories to the extent they seek documents that already have been provided to Plaintiff, are publicly available or otherwise equally available to Plaintiff, or would be more appropriately sought from third parties to whom subpoenas or requests could be directed, or through means that are more convenient, more efficient, more practical, less burdensome, or less expensive.
- 10. Janssen objects to Plaintiff's Definitions and Instructions to the extent they seek documents or information that would require Janssen to disclose trade secret, proprietary, and/or confidential information, except as provided for in the Protective Order agreed to by the parties.
- 11. Janssen objects to the Interrogatories to the extent that they incorporate incorrect assertions of fact or law. Janssen's Responses are not a concession that any incorporated assertions or conclusions of fact or law are correct.
- 12. Janssen objects to the Interrogatories to the extent they seek documents or information outside of the scope authorized in the Phased Discovery Order, including to the extent they seek discovery unrelated to support services provided by Plaintiff during her employment as an Area Business Specialist ("ABS") at Janssen to the physician practices specifically alleged in the Second Amended Complaint ("SAC"). See 2d Am. Compl. ¶¶ 175–76, 191–93. While Janssen agrees that documents and information beyond the scope authorized by the Court in the Phased Discovery Order may fall within the scope of subsequent discovery, requests for such documents and information are outside of the scope of the Court's guidance for

the narrow initial discovery that was to be the subject of Plaintiff's immediate requests. As such, Janssen objects to each Interrogatory to the extent that it seeks documents or information beyond the scope of the Phased Discovery Order.

- 13. Janssen objects to the definitions in Plaintiff's Instruction 3(a), (i), (l), (n), (o), (p), (q), (s), (u) and (w) as vague, ambiguous, overbroad, unduly burdensome, not calculated to lead to the discovery of admissible evidence, and beyond the scope authorized in the Phased Discovery Order.
- 14. Janssen objects to the definition of "Electronically stored information" or "ESI" in Plaintiff's Instruction 3(k) as overbroad and unduly burdensome. All productions of ESI made by Janssen pursuant to these Interrogatories will be made in accordance with, and subject to the provisions of, the ESI Protocol agreed to by the parties.
- 15. Janssen objects to Plaintiff's Definitions and Instructions, including Plaintiff's Instructions 3(i), 3(*I*), 3(w), and 6, to the extent they seek to impose obligations on entities that are distinct from Janssen, including, but not limited to, Janssen's parents, U.S. and non-U.S. subsidiaries, divisions, affiliates, predecessors, successors, agents, partners, limited partners, and independent contractors. By defining Janssen and "Defendant" to include entities that are distinct from Janssen and not parties to this action, Plaintiff improperly conflates Janssen with distinct entities that are third parties. Therefore, Janssen construes "Janssen," "Defendant," "You," and "Your" to refer only to Janssen and its employees. Janssen will respond to the Interrogatories based on a reasonable inquiry of individuals expected to possess the requested information.
- 16. Janssen objects to Instruction 12 to the extent it purports to impose requirements beyond those prescribed by Rule 26(b)(5) of the Federal Rules of Civil Procedure. Janssen will

log requested documents withheld from production as required by Rule 26(b)(5) and in accordance with, and subject to the provisions of, the Protective Order agreed to by the parties.

- 17. Janssen objects to Instructions 14(b) and 14(c) to the extent they seek information not reasonably available to Janssen from internal employment records as overbroad, unduly burdensome, not calculated to lead to the discovery of admissible evidence, and beyond the scope authorized in the Phased Discovery Order.
- 18. Janssen objects to Plaintiff's Interrogatories, Definitions, and Instructions, including Plaintiff's Instruction 8, to the extent they seek information before October 28, 2006 as outside the scope of this phase of discovery under the Phased Discovery Order.
- 19. Janssen objects to these Interrogatories to the extent they request information that is "not reasonably accessible because of undue burden or cost" under Fed. R. Civ. P. 26(b)(2)(B), including to the extent they request information that is in archived systems, files, or storage.

RESPONSES TO INTERROGATORY NO. 3, AND AMENDED INTERROGATORY NOS. 8 AND 18

INTERROGATORY NO. 3:

Identify each Employee who reviewed or analyzed the lawfulness of helping physicians open an IOI, including when each Employee performed the review or analysis and the Employee's position at the time of such review or analysis.

SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 3:

In addition to the foregoing General Objections, Janssen objects to this Interrogatory, to the extent it seeks information that is not related to support services provided by Plaintiff during her employment as an ABS at Janssen to the physician practices specifically alleged in the SAC, as outside the scope of this phase of discovery under the Phased Discovery Order. Janssen further objects that this Interrogatory is vague, ambiguous, and overbroad in its use of the term

"helping" and "physicians." Janssen further objects to this Interrogatory as overbroad, unduly burdensome, not proportional to the needs of the case, and not reasonably calculated to lead to the discovery of admissible evidence, particularly to the extent that it requests Janssen to "[i]dentify each Employee" who performed reviews or analysis over a 23-year time period of 1998 to the present, as well as the dates and Employee's position at the time of the reviews and analyses. Janssen further objects to this Interrogatory to the extent that it requests information protected by the attorney-client privilege, attorney work product protection, or any other applicable privilege or protection. Janssen further objects to this Interrogatory to the extent it purports to require a response prior to the completion of document production and depositions within this phase of discovery.

Subject to the foregoing general and specific objections, Janssen responds that it did not "help[] physicians open an IOI." Janssen states that its Healthcare Compliance ("HCC") department was involved in establishing rules and standards for ABS engagement with physician practices. Specifically, Janssen's HCC department created, promulgated, and enforced policies for the purpose of ensuring that Janssen's business practices complied with applicable federal, state, and local laws and regulations. The HCC department maintained a regularly updated manual of policies with which all Janssen employees were expected to comply. It held training sessions to provide direction to employees, including those in the sales and marketing departments, on the relevant policies. Tom Cornely (HCC Officer, Immunology, April 2013–2016) served as an HCC officer supporting the Immunology franchise during the time period when Janssen ABSs provided medical education and patient support services to rheumatology and gastroenterology physician practices. Additional HCC members who reviewed the medical education and patient support services at issue include Michael Schoeck (Director, HCC and

Privacy, October 2002–August 2008, Director, HCC, August 2008–December 2010), John "Chip" Franz (HCC Officer, October 2010–August 2014), Angela Wood (HCC Officer, November 2010–June 2014), Gina Giordano (HCC Officer, June 2009–October 2015), and Roger Kung (HCC Officer, 2011–2012).

Janssen has produced relevant and responsive HCC policies and training presentations, including policies related to Entertainment and Business Meals, the promotion of FDA-Regulated Products, and Consulting and Product-Related Items and Services Provided to Customers. Janssen has produced versions of these policies dating back to the early 2000s.

JANSSENBIO-011-00008078	JANSSENBIO-011-00008347	JANSSENBIO-013-00010691
JANSSENBIO-013-00014696	JANSSENBIO-013-00015412	JANSSENBIO-013-00019244
JANSSENBIO-018-00000001	JANSSENBIO-018-00000002	JANSSENBIO-018-00000021
JANSSENBIO-018-00000034	JANSSENBIO-018-00000044	JANSSENBIO-018-00000059
JANSSENBIO-018-00000067	JANSSENBIO-018-00000075	JANSSENBIO-018-00000080
JANSSENBIO-018-00000095	JANSSENBIO-018-00000099	JANSSENBIO-018-00000112
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	JANSSENBIO-037-00001348	JANSSENBIO-037-00001358	JANSSENBIO-008-00002497

Janssen further responds that the Promotional Review Committee ("PRC"), or its equivalent, reviewed each program challenged by Relator to ensure compliance with relevant applicable law. The PRC was responsible for evaluating all proposed promotional materials to ensure that promotional activity complied with both HCC policies and with relevant federal, state, and local laws and regulations, including the False Claims Act. Janssen has produced Standard Operating Procedures for the PRC, which outline the roles of various committee members and the processes underlying the committee's review.

JANSSENBIO-018-00001325	JANSSENBIO-018-00001266	JANSSENBIO-018-00001277
JANSSENBIO-018-00001260	JANSSENBIO-018-00001292	JANSSENBIO-018-00001305
JANSSENBIO-018-00001284	JANSSENBIO-018-00001322	

The PRC included members from various Janssen departments, including HCC Regulatory, HCC Privacy, Legal, and Medical. Membership on the PRC rotated on a frequent basis, and specific individuals who sat on the PRC, with respect to the medical education and patient support programs at issue, are listed on the PRC forms produced in this litigation.

JANSSENBIO-017-00023938	JANSSENBIO-017-00023983	JANSSENBIO-017-00024029
JANSSENBIO-017-00024028	JANSSENBIO-017-00024209	JANSSENBIO-017-00045687
JANSSENBIO-017-00022080	JANSSENBIO-017-00025415	JANSSENBIO-017-00032935
JANSSENBIO-017-00034424	JANSSENBIO-017-00034302	JANSSENBIO-017-00046154
JANSSENBIO-017-00046183	JANSSENBIO-017-00046233	JANSSENBIO-017-00046282
JANSSENBIO-017-00046300	JANSSENBIO-017-00046320	JANSSENBIO-017-00046341
JANSSENBIO-017-00046368	JANSSENBIO-017-00053659	JANSSENBIO-017-00065247
JANSSENBIO-017-00014092	JANSSENBIO-017-00014461	JANSSENBIO-017-00050760
JANSSENBIO-017-00051280	JANSSENBIO-017-00025077	JANSSENBIO-017-00025025
JANSSENBIO-017-00030065	JANSSENBIO-017-00030059	JANSSENBIO-017-00033923
JANSSENBIO-017-00033714	JANSSENBIO-017-00014652	JANSSENBIO-017-00014625
JANSSENBIO-017-00014583	JANSSENBIO-017-00014605	JANSSENBIO-017-00014558
JANSSENBIO-017-00014505	JANSSENBIO-017-00028314	JANSSENBIO-017-00028362
JANSSENBIO-017-00039859	JANSSENBIO-017-00039778	JANSSENBIO-017-00039896
JANSSENBIO-017-00039875	JANSSENBIO-017-00039938	JANSSENBIO-017-00039914
JANSSENBIO-017-00028269	JANSSENBIO-017-00028418	JANSSENBIO-017-00064955
JANSSENBIO-017-00065137	JANSSENBIO-017-00053230	JANSSENBIO-017-00053653
JANSSENBIO-017-00048186	JANSSENBIO-017-00048283	JANSSENBIO-017-00048317
JANSSENBIO-017-00026947	JANSSENBIO-017-00016162	JANSSENBIO-017-00016140

JANSSENBIO-017-00059669	JANSSENBIO-017-00060154	JANSSENBIO-017-00063131
JANSSENBIO-017-00063531	JANSSENBIO-017-00022414	JANSSENBIO-017-00022415
JANSSENBIO-017-00022353	JANSSENBIO-017-00022459	JANSSENBIO-017-00022427
JANSSENBIO-017-00026870	JANSSENBIO-017-00026859	JANSSENBIO-017-00026228
JANSSENBIO-017-00028971	JANSSENBIO-017-00028682	JANSSENBIO-017-00026892
JANSSENBIO-017-00026880	JANSSENBIO-017-00039554	JANSSENBIO-017-00039481
JANSSENBIO-017-00039722	JANSSENBIO-017-00039710	JANSSENBIO-017-00044681
JANSSENBIO-017-00044363	JANSSENBIO-017-00044692	JANSSENBIO-017-00034875
JANSSENBIO-017-00034510	JANSSENBIO-017-00046974	JANSSENBIO-017-00046942
JANSSENBIO-017-00047007	JANSSENBIO-017-00046989	JANSSENBIO-017-00047040
JANSSENBIO-017-00047022	JANSSENBIO-021-00002827	JANSSENBIO-017-00022750
JANSSENBIO-017-00022575	JANSSENBIO-017-00045200	JANSSENBIO-017-00044880
JANSSENBIO-017-00030031	JANSSENBIO-017-00023276	JANSSENBIO-017-00023154
JANSSENBIO-017-00051846	JANSSENBIO-017-00052068	JANSSENBIO-017-00052078
JANSSENBIO-017-00052094	JANSSENBIO-017-00052113	JANSSENBIO-020-00003296
JANSSENBIO-020-00003485	JANSSENBIO-017-00021023	JANSSENBIO-017-00021372
JANSSENBIO-017-00032825	JANSSENBIO-017-00031647	JANSSENBIO-017-00036626
JANSSENBIO-017-00035897	JANSSENBIO-017-00025562	JANSSENBIO-017-00027177
JANSSENBIO-017-00027061	JANSSENBIO-017-00015977	JANSSENBIO-017-00015803
JANSSENBIO-017-00040227	JANSSENBIO-017-00040033	JANSSENBIO-017-00047768
JANSSENBIO-017-00047662	JANSSENBIO-017-00047844	JANSSENBIO-017-00047961
JANSSENBIO-017-00035354	JANSSENBIO-017-00035367	JANSSENBIO-017-00035386
JANSSENBIO-017-00035409	JANSSENBIO-017-00035247	JANSSENBIO-017-00035220
JANSSENBIO-017-00035345	JANSSENBIO-017-00035333	JANSSENBIO-017-00035322
JANSSENBIO-017-00035295	JANSSENBIO-017-00045741	JANSSENBIO-017-00045751
JANSSENBIO-017-00045787	JANSSENBIO-021-00002241	JANSSENBIO-021-00002248
JANSSENBIO-021-00002266	JANSSENBIO-021-00002273	JANSSENBIO-021-00002283
JANSSENBIO-021-00002351	JANSSENBIO-021-00002474	JANSSENBIO-021-00002564
JANSSENBIO-021-00002741	JANSSENBIO-021-00003077	JANSSENBIO-021-00003338
JANSSENBIO-021-00003600	JANSSENBIO-021-00003743	JANSSENBIO-021-00003831
JANSSENBIO-021-00003962	JANSSENBIO-030-00005366	JANSSENBIO-031-00006684
JANSSENBIO-032-00000959	JANSSENBIO-032-00000962	JANSSENBIO-031-00005015
JANSSENBIO-032-00000716	JANSSENBIO-031-00005125	JANSSENBIO-030-00003829
JANSSENBIO-030-00007626	JANSSENBIO-030-00006482	JANSSENBIO-030-00006487
JANSSENBIO-031-00005015	JANSSENBIO-032-00000716	JANSSENBIO-031-00005125
JANSSENBIO-030-00003829	JANSSENBIO-030-00007626	JANSSENBIO-030-00006482
JANSSENBIO-030-00006487	JANSSENBIO-031-00002904	JANSSENBIO-031-00013884
JANSSENBIO-031-00013889	JANSSENBIO-031-00013897	JANSSENBIO-030-00004786
JANSSENBIO-030-00004793	JANSSENBIO-030-00004813	JANSSENBIO-030-00004819
JANSSENBIO-031-00012555	JANSSENBIO-031-00008715	JANSSENBIO-031-00011492
JANSSENBIO-030-00009504	JANSSENBIO-031-00002531	JANSSENBIO-031-00002758
JANSSENBIO-032-00000828	JANSSENBIO-030-00005342	JANSSENBIO-030-00005346
JANSSENBIO-031-00004950	JANSSENBIO-032-00000712	JANSSENBIO-030-00003722
JANSSENBIO-030-00003688	JANSSENBIO-031-00005361	JANSSENBIO-030-00004009
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JANSSENBIO-030-00004013	JANSSENBIO-030-00004106	JANSSENBIO-030-00004057
JANSSENBIO-031-00015265	JANSSENBIO-031-00000954	JANSSENBIO-030-00000741
JANSSENBIO-030-00000788	JANSSENBIO-032-00000766	JANSSENBIO-031-00006658
JANSSENBIO-031-00002451	JANSSENBIO-031-00002452	JANSSENBIO-031-00002399
JANSSENBIO-031-00002293	JANSSENBIO-031-00002397	JANSSENBIO-031-00002297
JANSSENBIO-031-00005505	JANSSENBIO-030-00004094	JANSSENBIO-031-00005501
JANSSENBIO-030-00004100	JANSSENBIO-030-00004101	JANSSENBIO-031-00007275
JANSSENBIO-030-00005994	JANSSENBIO-030-00005999	JANSSENBIO-030-00006012
JANSSENBIO-030-00009859	JANSSENBIO-031-00011737	JANSSENBIO-030-00009830
JANSSENBIO-031-00003254	JANSSENBIO-031-00003250	JANSSENBIO-032-00000386
JANSSENBIO-032-00000374	JANSSENBIO-032-00000420	JANSSENBIO-030-00002653
JANSSENBIO-031-00012670	JANSSENBIO-031-00012896	JANSSENBIO-031-00012664
JANSSENBIO-031-00012665	JANSSENBIO-031-00012666	JANSSENBIO-031-00012667
JANSSENBIO-031-00012668	JANSSENBIO-030-00001814	JANSSENBIO-031-00001863
JANSSENBIO-031-00001880	JANSSENBIO-030-00001810	JANSSENBIO-030-00000991
JANSSENBIO-030-00000995	JANSSENBIO-032-00000865	JANSSENBIO-030-00005352
JANSSENBIO-031-00006668	JANSSENBIO-031-00001644	JANSSENBIO-031-00001636
JANSSENBIO-031-00001640	JANSSENBIO-030-00001521	JANSSENBIO-030-00001662
JANSSENBIO-030-00003133	JANSSENBIO-030-00003541	JANSSENBIO-031-00005611
JANSSENBIO-031-00005607	JANSSENBIO-030-00004154	JANSSENBIO-030-00004155
JANSSENBIO-030-00005842	JANSSENBIO-030-00005726	JANSSENBIO-030-00005765
JANSSENBIO-031-00006495	JANSSENBIO-031-00006188	JANSSENBIO-030-00004911
JANSSENBIO-031-00006189	JANSSENBIO-031-00006190	

In addition to legal personnel who served on the PRC over the years—which included Freddy Jimenez (September 1999–January 2016), Kathleen Hamill (Assistant General Counsel, April 2000–present), Chris Guiton (Assistant General Counsel, July 2007–present), and John Vaughan (Senior Counsel, 2007–June 2012)—Deidre Meehan (Assistant General Counsel, Regulatory, August 2007–December 2020) and Daryl Todd (Assistant General Counsel, April 2010–present) provided privileged legal advice concerning medical education and patient support services provided by ABSs.

AMENDED INTERROGATORY NO. 8:

Identify the Employees (excluding Area Business Specialists and Regional Business Managers) who are or were responsible for reviewing or analyzing the lawfulness of providing

the Infusion Services Review (also known as "IBiz," "Infusion Business Review," "Managing Biologics in the Physician Office," "MBPO," "Account Review," and "Business Review") presentation, program, or consultative session to IOI Accounts (including the Phase 1 Accounts), including when each Employee performed the review or analysis and the Employee's position at the time of such review or analysis.

SUPPLEMENTAL RESPONSE TO AMENDED INTERROGATORY NO. 8:

In addition to the foregoing General Objections, Janssen objects to this Interrogatory, to the extent it seeks information that is not related to support services provided by Plaintiff during her employment as an ABS at Janssen to the physician practices specifically alleged in the SAC, as outside the scope of this phase of discovery under the Phased Discovery Order. Janssen further objects that this Interrogatory is vague, ambiguous, and overbroad in its use of the terms "Infusion Services Review," "presentation," "program," "consultative session," and "IOI Accounts." Janssen further objects to this Interrogatory as overbroad, unduly burdensome, not proportional to the needs of the case, and not reasonably calculated to lead to the discovery of admissible evidence, particularly to the extent that it requests Janssen to identify each Employee other than ABSs and Regional Business Managers ("RBMs") who had authority over reviews or analyses over a 23-year time period of 1998 to the present, as well as the dates and Employee's position at the time of the reviews and analyses. Janssen further objects to this Interrogatory to the extent it purports to require a response prior to the completion of document production and depositions within this phase of discovery.

Subject to the foregoing general and specific objections, Janssen responds that its

Healthcare Compliance ("HCC") department was involved in establishing recommended

practices and standards for ABS engagement with physician practices. Specifically, Janssen's

HCC department created, promulgated, and enforced policies for the purpose of ensuring that Janssen's business practices complied with applicable federal, state, and local laws and regulations. The HCC department maintained a regularly updated manual of policies with which all Janssen employees were expected to comply. It held training sessions to provide direction to employees, including those in the sales and marketing departments, on the relevant policies. Tom Cornely (HCC Officer, Immunology, April 2013–2016) served as an HCC officer supporting the Immunology franchise during the time period when Janssen ABSs provided medical education and patient support services to rheumatology and gastroenterology physician practices.

Additional HCC members that reviewed the medical education and patient support services at issue include Michael Schoeck (Director, HCC and Privacy, October 2002–August 2008, Director, HCC, August 2008–December 2010), John "Chip" Franz (HCC Officer, October 2010–August 2014), Angela Wood (HCC Officer, November 2010–June 2014), Gina Giordano (HCC Officer, June 2009–October 2015), and Roger Kung (HCC Officer, 2011–2012).

Janssen has produced relevant and responsive HCC policies and training presentations, including policies related to Entertainment and Business Meals, the promotion of FDA-Regulated Products, and Consulting and Product-Related Items and Services Provided to Customers. Janssen has produced versions of these policies dating back to the early 2000s.

JANSSENBIO-011-00008078	JANSSENBIO-011-00008347	JANSSENBIO-013-00010691
JANSSENBIO-013-00014696	JANSSENBIO-013-00015412	JANSSENBIO-013-00019244
JANSSENBIO-018-00000001	JANSSENBIO-018-00000002	JANSSENBIO-018-00000021
JANSSENBIO-018-00000034	JANSSENBIO-018-00000044	JANSSENBIO-018-00000059
JANSSENBIO-018-00000067	JANSSENBIO-018-00000075	JANSSENBIO-018-00000080
JANSSENBIO-018-00000095	JANSSENBIO-018-00000099	JANSSENBIO-018-00000112
JANSSENBIO-018-00000120	JANSSENBIO-018-00000128	JANSSENBIO-018-00000139
JANSSENBIO-018-00000147	JANSSENBIO-018-00000161	JANSSENBIO-018-00000173
JANSSENBIO-018-00000183	JANSSENBIO-018-00000191	JANSSENBIO-018-00000202
JANSSENBIO-018-00000210	JANSSENBIO-018-00000217	JANSSENBIO-018-00000230
JANSSENBIO-018-00000236	JANSSENBIO-018-00000240	JANSSENBIO-018-00000245
JANSSENBIO-018-00000249	JANSSENBIO-018-00000260	JANSSENBIO-018-00000268

JANSSENBIO-018-00000276	JANSSENBIO-018-00000287	JANSSENBIO-018-00000295
JANSSENBIO-018-00000309	JANSSENBIO-018-00000314	JANSSENBIO-018-00000326
JANSSENBIO-018-00000336	JANSSENBIO-018-00000351	JANSSENBIO-018-00000359
JANSSENBIO-018-00000370	JANSSENBIO-018-00000378	JANSSENBIO-018-00000385
JANSSENBIO-018-00000398	JANSSENBIO-018-00000404	JANSSENBIO-018-00000408
JANSSENBIO-018-00000414	JANSSENBIO-018-00000425	JANSSENBIO-018-00000433
JANSSENBIO-018-00000441	JANSSENBIO-018-00000452	JANSSENBIO-018-00000460
JANSSENBIO-018-00000474	JANSSENBIO-018-00000484	JANSSENBIO-018-00000499
JANSSENBIO-018-00000508	JANSSENBIO-018-00000520	JANSSENBIO-018-00000528
JANSSENBIO-018-00000535	JANSSENBIO-018-00000549	JANSSENBIO-018-00000555
JANSSENBIO-018-00000559	JANSSENBIO-018-00000565	JANSSENBIO-018-00000566
JANSSENBIO-018-00000569	JANSSENBIO-018-00000580	JANSSENBIO-018-00000588
JANSSENBIO-018-00000596	JANSSENBIO-018-00000610	JANSSENBIO-018-00000621
JANSSENBIO-018-00000629	JANSSENBIO-018-00000641	JANSSENBIO-018-00000646
JANSSENBIO-018-00000650	JANSSENBIO-018-00000660	JANSSENBIO-018-00000675
JANSSENBIO-018-00000684	JANSSENBIO-018-00000696	JANSSENBIO-018-00000704
JANSSENBIO-018-00000711	JANSSENBIO-018-00000725	JANSSENBIO-018-00000731
JANSSENBIO-018-00000735	JANSSENBIO-018-00000741	JANSSENBIO-018-00000742
JANSSENBIO-018-00000745	JANSSENBIO-018-00000753	JANSSENBIO-018-00000761
JANSSENBIO-018-00000775	JANSSENBIO-018-00000786	JANSSENBIO-018-00000794
JANSSENBIO-018-00000806	JANSSENBIO-018-00000810	JANSSENBIO-018-00000812
JANSSENBIO-018-00000816	JANSSENBIO-018-00000818	JANSSENBIO-018-00000821
JANSSENBIO-018-00000822	JANSSENBIO-018-00000826	JANSSENBIO-018-00000828
JANSSENBIO-018-00000832	JANSSENBIO-018-00000834	JANSSENBIO-018-00000837
JANSSENBIO-018-00000838	JANSSENBIO-018-00000839	JANSSENBIO-018-00000852
JANSSENBIO-018-00000853	JANSSENBIO-018-00000866	JANSSENBIO-018-00000871
JANSSENBIO-018-00000873	JANSSENBIO-018-00000878	JANSSENBIO-018-00000880
JANSSENBIO-018-00000884	JANSSENBIO-018-00000888	JANSSENBIO-018-00000904
JANSSENBIO-018-00000908	JANSSENBIO-018-00000912	JANSSENBIO-018-00000928
JANSSENBIO-018-00000936	JANSSENBIO-018-00000941	JANSSENBIO-018-00000957
JANSSENBIO-018-00000963	JANSSENBIO-018-00000977	JANSSENBIO-018-00000997
JANSSENBIO-018-00001010	JANSSENBIO-018-00001021	JANSSENBIO-018-00001029
JANSSENBIO-018-00001037	JANSSENBIO-018-00001050	JANSSENBIO-018-00001055
JANSSENBIO-018-00001071	JANSSENBIO-018-00001077	JANSSENBIO-018-00001091
JANSSENBIO-018-00001104	JANSSENBIO-018-00001115	JANSSENBIO-018-00001123
JANSSENBIO-018-00001125	JANSSENBIO-018-00001127	JANSSENBIO-018-00001129
JANSSENBIO-018-00001150	JANSSENBIO-018-00001156	JANSSENBIO-018-00001251
JANSSENBIO-031-00016316	JANSSENBIO-031-00016333	JANSSENBIO-031-00016342
JANSSENBIO-031-00016356	JANSSENBIO-031-00016371	JANSSENBIO-031-00016402
JANSSENBIO-031-00016378	JANSSENBIO-031-00016386	JANSSENBIO-031-00016453
JANSSENBIO-031-00016404	JANSSENBIO-031-00016416	JANSSENBIO-031-00016545
JANSSENBIO-031-00016491	JANSSENBIO-031-00016492	JANSSENBIO-031-00016548
JANSSENBIO-031-00016546	JANSSENBIO-031-00016547	JANSSENBIO-037-00000270
JANSSENBIO-037-00000003	JANSSENBIO-037-00000125	JANSSENBIO-037-00000312

JANSSENBIO-037-00000304	JANSSENBIO-037-00000307	JANSSENBIO-037-00000333
JANSSENBIO-037-00000318	JANSSENBIO-037-00000327	JANSSENBIO-037-00000799
JANSSENBIO-037-00000335	JANSSENBIO-037-00000339	JANSSENBIO-037-00001006
JANSSENBIO-037-00000641	JANSSENBIO-037-00000348	JANSSENBIO-037-00001046
JANSSENBIO-037-00000844	JANSSENBIO-037-00000791	JANSSENBIO-037-00001075
JANSSENBIO-037-00001010	JANSSENBIO-037-00001028	JANSSENBIO-037-00001100
JANSSENBIO-037-00001051	JANSSENBIO-037-00001071	JANSSENBIO-037-00001133
JANSSENBIO-037-00001085	JANSSENBIO-037-00001090	JANSSENBIO-037-00001153
JANSSENBIO-037-00001104	JANSSENBIO-037-00001117	JANSSENBIO-037-00001186
JANSSENBIO-037-00001140	JANSSENBIO-037-00001147	JANSSENBIO-037-00001249
JANSSENBIO-037-00001157	JANSSENBIO-037-00001169	JANSSENBIO-037-00001325
JANSSENBIO-037-00001210	JANSSENBIO-037-00001234	JANSSENBIO-037-00001340
JANSSENBIO-037-00001252	JANSSENBIO-037-00001295	JANSSENBIO-037-00001361
JANSSENBIO-037-00001332	JANSSENBIO-037-00001335	JANSSENBIO-011-00007708
JANSSENBIO-037-00001348	JANSSENBIO-037-00001358	JANSSENBIO-008-00002497

Janssen further responds that the Promotional Review Committee ("PRC"), or its equivalent, reviewed each program challenged by Relator to ensure compliance with relevant applicable law. The PRC was responsible for evaluating all proposed promotional materials to ensure that promotional activity complied with both HCC policies and with relevant federal, state, and local laws and regulations, including the False Claims Act. Janssen has produced Standard Operating Procedures for the PRC, which outline the roles of various committee members and the processes underlying the committee's review.

JANSSENBIO-018-00001325	JANSSENBIO-018-00001266	JANSSENBIO-018-00001277
JANSSENBIO-018-00001260	JANSSENBIO-018-00001292	JANSSENBIO-018-00001305
JANSSENBIO-018-00001284	JANSSENBIO-018-00001322	

The PRC included members from various Janssen departments, including HCC Regulatory, HCC Privacy, Legal, and Medical. Membership on the PRC rotated on a frequent basis, and specific individuals who sat on the PRC, with respect to the medical education and patient support programs at issue, are listed on the PRC forms produced in this litigation.

JANSSENBIO-017-00023938	JANSSENBIO-017-00023983	JANSSENBIO-017-00024029
JANSSENBIO-017-00024028	JANSSENBIO-017-00024209	JANSSENBIO-017-00045687
JANSSENBIO-017-00022080	JANSSENBIO-017-00025415	JANSSENBIO-017-00032935

JANSSENBIO-017-00034424	JANSSENBIO-017-00034302	JANSSENBIO-017-00046154
JANSSENBIO-017-00046183	JANSSENBIO-017-00046233	JANSSENBIO-017-00046282
JANSSENBIO-017-00046300	JANSSENBIO-017-00046320	JANSSENBIO-017-00046341
JANSSENBIO-017-00046368	JANSSENBIO-017-00053659	JANSSENBIO-017-00065247
JANSSENBIO-017-00014092	JANSSENBIO-017-00014461	JANSSENBIO-017-00050760
JANSSENBIO-017-00051280	JANSSENBIO-017-00025077	JANSSENBIO-017-00025025
JANSSENBIO-017-00030065	JANSSENBIO-017-00030059	JANSSENBIO-017-00033923
JANSSENBIO-017-00033714	JANSSENBIO-017-00014652	JANSSENBIO-017-00014625
JANSSENBIO-017-00014583	JANSSENBIO-017-00014605	JANSSENBIO-017-00014558
JANSSENBIO-017-00014505	JANSSENBIO-017-00028314	JANSSENBIO-017-00028362
JANSSENBIO-017-00039859	JANSSENBIO-017-00039778	JANSSENBIO-017-00039896
JANSSENBIO-017-00039875	JANSSENBIO-017-00039938	JANSSENBIO-017-00039914
JANSSENBIO-017-00028269	JANSSENBIO-017-00028418	JANSSENBIO-017-00064955
JANSSENBIO-017-00065137	JANSSENBIO-017-00053230	JANSSENBIO-017-00053653
JANSSENBIO-017-00048186	JANSSENBIO-017-00048283	JANSSENBIO-017-00048317
JANSSENBIO-017-00026947	JANSSENBIO-017-00016162	JANSSENBIO-017-00016140
JANSSENBIO-017-00059669	JANSSENBIO-017-00060154	JANSSENBIO-017-00063131
JANSSENBIO-017-00063531	JANSSENBIO-017-00022414	JANSSENBIO-017-00022415
JANSSENBIO-017-00022353	JANSSENBIO-017-00022459	JANSSENBIO-017-00022427
JANSSENBIO-017-00026870	JANSSENBIO-017-00026859	JANSSENBIO-017-00026228
JANSSENBIO-017-00028971	JANSSENBIO-017-00028682	JANSSENBIO-017-00026892
JANSSENBIO-017-00026880	JANSSENBIO-017-00039554	JANSSENBIO-017-00039481
JANSSENBIO-017-00039722	JANSSENBIO-017-00039710	JANSSENBIO-017-00044681
JANSSENBIO-017-00044363	JANSSENBIO-017-00044692	JANSSENBIO-017-00034875
JANSSENBIO-017-00034510	JANSSENBIO-017-00046974	JANSSENBIO-017-00046942
JANSSENBIO-017-00047007	JANSSENBIO-017-00046989	JANSSENBIO-017-00047040
JANSSENBIO-017-00047022	JANSSENBIO-021-00002827	JANSSENBIO-017-00022750
JANSSENBIO-017-00022575	JANSSENBIO-017-00045200	JANSSENBIO-017-00044880
JANSSENBIO-017-00030031	JANSSENBIO-017-00023276	JANSSENBIO-017-00023154
JANSSENBIO-017-00051846	JANSSENBIO-017-00052068	JANSSENBIO-017-00052078
JANSSENBIO-017-00052094	JANSSENBIO-017-00052113	JANSSENBIO-020-00003296
JANSSENBIO-020-00003485	JANSSENBIO-017-00021023	JANSSENBIO-017-00021372
JANSSENBIO-017-00032825	JANSSENBIO-017-00031647	JANSSENBIO-017-00036626
JANSSENBIO-017-00035897	JANSSENBIO-017-00025562	JANSSENBIO-017-00027177
JANSSENBIO-017-00027061	JANSSENBIO-017-00015977	JANSSENBIO-017-00015803
JANSSENBIO-017-00040227	JANSSENBIO-017-00040033	JANSSENBIO-017-00047768
JANSSENBIO-017-00047662	JANSSENBIO-017-00047844	JANSSENBIO-017-00047961
JANSSENBIO-017-00035354	JANSSENBIO-017-00035367	JANSSENBIO-017-00035386
JANSSENBIO-017-00035409	JANSSENBIO-017-00035247	JANSSENBIO-017-00035220
JANSSENBIO-017-00035345	JANSSENBIO-017-00035333	JANSSENBIO-017-00035322
JANSSENBIO-017-00035295	JANSSENBIO-017-00045741	JANSSENBIO-017-00045751
JANSSENBIO-017-00045787	JANSSENBIO-021-00002241	JANSSENBIO-021-00002248
JANSSENBIO-021-00002266	JANSSENBIO-021-00002273	JANSSENBIO-021-00002283
JANSSENBIO-021-00002351	JANSSENBIO-021-00002474	JANSSENBIO-021-00002564

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JANSSENBIO-021-00002741	JANSSENBIO-021-00003077	JANSSENBIO-021-00003338
JANSSENBIO-021-00003600	JANSSENBIO-021-00003743	JANSSENBIO-021-00003831
JANSSENBIO-021-00003962	JANSSENBIO-030-00005366	JANSSENBIO-031-00006684
JANSSENBIO-032-00000959	JANSSENBIO-032-00000962	JANSSENBIO-031-00005015
JANSSENBIO-032-00000716	JANSSENBIO-031-00005125	JANSSENBIO-030-00003829
JANSSENBIO-030-00007626	JANSSENBIO-030-00006482	JANSSENBIO-030-00006487
JANSSENBIO-031-00005015	JANSSENBIO-032-00000716	JANSSENBIO-031-00005125
JANSSENBIO-030-00003829	JANSSENBIO-030-00007626	JANSSENBIO-030-00006482
JANSSENBIO-030-00006487	JANSSENBIO-031-00002904	JANSSENBIO-031-00013884
JANSSENBIO-031-00013889	JANSSENBIO-031-00013897	JANSSENBIO-030-00004786
JANSSENBIO-030-00004793	JANSSENBIO-030-00004813	JANSSENBIO-030-00004819
JANSSENBIO-031-00012555	JANSSENBIO-031-00008715	JANSSENBIO-031-00011492
JANSSENBIO-030-00009504	JANSSENBIO-031-00002531	JANSSENBIO-031-00002758
JANSSENBIO-032-00000828	JANSSENBIO-030-00005342	JANSSENBIO-030-00005346
JANSSENBIO-031-00004950	JANSSENBIO-032-00000712	JANSSENBIO-030-00003722
JANSSENBIO-030-00003688	JANSSENBIO-031-00005361	JANSSENBIO-030-00004009
JANSSENBIO-030-00004013	JANSSENBIO-030-00004106	JANSSENBIO-030-00004057
JANSSENBIO-031-00015265	JANSSENBIO-031-00000954	JANSSENBIO-030-00000741
JANSSENBIO-030-00000788	JANSSENBIO-032-00000766	JANSSENBIO-031-00006658
JANSSENBIO-031-00002451	JANSSENBIO-031-00002452	JANSSENBIO-031-00002399
JANSSENBIO-031-00002293	JANSSENBIO-031-00002397	JANSSENBIO-031-00002297
JANSSENBIO-031-00005505	JANSSENBIO-030-00004094	JANSSENBIO-031-00005501
JANSSENBIO-030-00004100	JANSSENBIO-030-00004101	JANSSENBIO-031-00007275
JANSSENBIO-030-00005994	JANSSENBIO-030-00005999	JANSSENBIO-030-00006012
JANSSENBIO-030-00009859	JANSSENBIO-031-00011737	JANSSENBIO-030-00009830
JANSSENBIO-031-00003254	JANSSENBIO-031-00003250	JANSSENBIO-032-00000386
JANSSENBIO-032-00000374	JANSSENBIO-032-00000420	JANSSENBIO-030-00002653
JANSSENBIO-031-00012670	JANSSENBIO-031-00012896	JANSSENBIO-031-00012664
JANSSENBIO-031-00012665	JANSSENBIO-031-00012666	JANSSENBIO-031-00012667
JANSSENBIO-031-00012668	JANSSENBIO-030-00001814	JANSSENBIO-031-00001863
JANSSENBIO-031-00001880	JANSSENBIO-030-00001810	JANSSENBIO-030-00000991
JANSSENBIO-030-00000995	JANSSENBIO-032-00000865	JANSSENBIO-030-00005352
JANSSENBIO-031-00006668	JANSSENBIO-031-00001644	JANSSENBIO-031-00001636
JANSSENBIO-031-00001640	JANSSENBIO-030-00001521	JANSSENBIO-030-00001662
JANSSENBIO-030-00003133	JANSSENBIO-030-00003541	JANSSENBIO-031-00005611
JANSSENBIO-031-00005607	JANSSENBIO-030-00004154	JANSSENBIO-030-00004155
JANSSENBIO-030-00005842	JANSSENBIO-030-00005726	JANSSENBIO-030-00005765
JANSSENBIO-031-00006495	JANSSENBIO-031-00006188	JANSSENBIO-030-00004911
JANSSENBIO-031-00006189	JANSSENBIO-031-00006190	
L	l .	

In addition to legal personnel who served on the PRC over the years—which included Freddy Jimenez (September 1999–January 2016), Kathleen Hamill (Assistant General Counsel, April 2000–present), Chris Guiton (Assistant General Counsel, July 2007–present), and John

Vaughan (Senior Counsel, 2007–June 2012)—Deidre Meehan (Assistant General Counsel, Regulatory, August 2007–December 2020) and Daryl Todd (Assistant General Counsel, April 2010–present) provided privileged legal advice concerning medical education and patient support services provided by ABSs.

AMENDED INTERROGATORY NO. 18:

For each of presentation, resource, or program described below, identify when you began and, if applicable, stopped directing Area Business Specialists (including Plaintiff) and/or any Outside Consultant to utilize the presentation, resource, or program in connection with providing IOI Support to IOI Accounts (including the Phase 1 Accounts):

- (1) IV Therapy: An Important Option for Your Patients (Why IV)
- (2) Infusion suite layout plan/infusion suite model
- (3) Infusion Optimization Modeler (IOM)
- (4) Efficiency checklist
- (5) Account Review
- (6) Managing Biologics in the Physician Office (MBPO)
- (7) Infusion Services Review
- (8) Infusion Business Review (IBiz)
- (9) Optimizing patient scheduling and infusion capacity
- (10) Proactive Practice Management
- (11) Payer Management
- (12) Payer Relationship Management
- (13) Private Payer Contracting Considerations for Remicade
- (14) Negotiating Payer Contracts
- (15) Contracting, acquiring drug, and managing payers
- (16) Raising the Infusion Suite Experience (RISE)
- (17) Enhancing quality measures, patient experience, and satisfaction
- (18) Protocols and Standard Operating Procedures
- (19) Optimizing your prior authorization/benefit investigations workflows
- (20) Utilizing alternative approaches to mitigate risk with buy-and-bill
- (21) Instituting best practice standard operating procedures (SOPs) and clinical protocols
- (22) Preparing the total office for ICD-10
- (23) Electronic Medical Records and Meaningful Use
- (24) Achieving Meaningful Use 2 with electronic health records
- (25) Vial Trend Update
- (26) Controlling and managing the infusible inventory
- (27) Inventory and Supply Management
- (28) Infusion Referrals: Improving the Continuity of Care

- (29) Enhancing the continuity of care with inbound and/or outbound referrals
- (30) Ambulatory Surgical Centers and Infusion Services
- (31) Successful Infusion Suite Management

SUPPLEMENTAL RESPONSE TO AMENDED INTERROGATORY NO. 18:

In addition to the foregoing General Objections, Janssen objects to this Interrogatory, to the extent it seeks information that is not related to support services provided by Plaintiff during her employment as an ABS at Janssen to the physician practices specifically alleged in the SAC, as outside the scope of this phase of discovery under the Phased Discovery Order. Janssen further objects that this Interrogatory is vague, ambiguous, and overbroad in its use of the term "Outside Consultant," "presentation," "resource," "program," "IOI Support," "IOI Accounts," and in its identification of 31 specific presentations. Janssen further objects that, to the extent this Interrogatory seeks information about specific presentations dated prior to October 2006, this request is unduly burdensome and goes beyond the scope of discovery ordered by the Judge Saylor. Janssen further objects to this Interrogatory in that it includes 31 distinct subparts and thus represents 31 separate interrogatories. Janssen further objects to this Interrogatory to the extent it purports to require a response prior to the completion of document production and depositions within this phase of discovery.

Janssen further objects to the extent that no such presentations, resources, or programs with the name identified in Amended Interrogatory No. 18 exist. In its response, therefore, Janssen provides information related to presentations, resources, or programs with similar titles or content, to the extent any such presentations, resources, or programs have been identified after a reasonable search.

Subject to the foregoing general and specific objections, Janssen states that before medical education and patient support resources are provided to rheumatology and

gastroenterology practices, they go through an approval process by Janssen's PRC or its equivalent. Janssen has produced PRC records of approved presentations, including available information on the approval dates of each presentation in the following documents:

JANSSENBIO-017-00023938	JANSSENBIO-017-00023983	JANSSENBIO-017-00024029
JANSSENBIO-017-00024028	JANSSENBIO-017-00024209	JANSSENBIO-017-00045687
JANSSENBIO-017-00022080	JANSSENBIO-017-00025415	JANSSENBIO-017-00032935
JANSSENBIO-017-00034424	JANSSENBIO-017-00034302	JANSSENBIO-017-00046154
JANSSENBIO-017-00046183	JANSSENBIO-017-00046233	JANSSENBIO-017-00046282
JANSSENBIO-017-00046300	JANSSENBIO-017-00046320	JANSSENBIO-017-00046341
JANSSENBIO-017-00046368	JANSSENBIO-017-00053659	JANSSENBIO-017-00065247
JANSSENBIO-017-00014092	JANSSENBIO-017-00014461	JANSSENBIO-017-00050760
JANSSENBIO-017-00051280	JANSSENBIO-017-00025077	JANSSENBIO-017-00025025
JANSSENBIO-017-00030065	JANSSENBIO-017-00030059	JANSSENBIO-017-00033923
JANSSENBIO-017-00033714	JANSSENBIO-017-00014652	JANSSENBIO-017-00014625
JANSSENBIO-017-00014583	JANSSENBIO-017-00014605	JANSSENBIO-017-00014558
JANSSENBIO-017-00014505	JANSSENBIO-017-00028314	JANSSENBIO-017-00028362
JANSSENBIO-017-00039859	JANSSENBIO-017-00039778	JANSSENBIO-017-00039896
JANSSENBIO-017-00039875	JANSSENBIO-017-00039938	JANSSENBIO-017-00039914
JANSSENBIO-017-00028269	JANSSENBIO-017-00028418	JANSSENBIO-017-00064955
JANSSENBIO-017-00065137	JANSSENBIO-017-00053230	JANSSENBIO-017-00053653
JANSSENBIO-017-00048186	JANSSENBIO-017-00048283	JANSSENBIO-017-00048317
JANSSENBIO-017-00026947	JANSSENBIO-017-00016162	JANSSENBIO-017-00016140
JANSSENBIO-017-00059669	JANSSENBIO-017-00060154	JANSSENBIO-017-00063131
JANSSENBIO-017-00063531	JANSSENBIO-017-00022414	JANSSENBIO-017-00022415
JANSSENBIO-017-00022353	JANSSENBIO-017-00022459	JANSSENBIO-017-00022427
JANSSENBIO-017-00026870	JANSSENBIO-017-00026859	JANSSENBIO-017-00026228
JANSSENBIO-017-00028971	JANSSENBIO-017-00028682	JANSSENBIO-017-00026892
JANSSENBIO-017-00026880	JANSSENBIO-017-00039554	JANSSENBIO-017-00039481
JANSSENBIO-017-00039722	JANSSENBIO-017-00039710	JANSSENBIO-017-00044681
JANSSENBIO-017-00044363	JANSSENBIO-017-00044692	JANSSENBIO-017-00034875
JANSSENBIO-017-00034510	JANSSENBIO-017-00046974	JANSSENBIO-017-00046942
JANSSENBIO-017-00047007	JANSSENBIO-017-00046989	JANSSENBIO-017-00047040
JANSSENBIO-017-00047022	JANSSENBIO-021-00002827	JANSSENBIO-017-00022750
JANSSENBIO-017-00022575	JANSSENBIO-017-00045200	JANSSENBIO-017-00044880
JANSSENBIO-017-00030031	JANSSENBIO-017-00023276	JANSSENBIO-017-00023154
JANSSENBIO-017-00051846	JANSSENBIO-017-00052068	JANSSENBIO-017-00052078
JANSSENBIO-017-00052094	JANSSENBIO-017-00052113	JANSSENBIO-020-00003296
JANSSENBIO-020-00003485	JANSSENBIO-017-00021023	JANSSENBIO-017-00021372
JANSSENBIO-017-00032825	JANSSENBIO-017-00031647	JANSSENBIO-017-00036626
JANSSENBIO-017-00035897	JANSSENBIO-017-00025562	JANSSENBIO-017-00027177
JANSSENBIO-017-00027061	JANSSENBIO-017-00015977	JANSSENBIO-017-00015803
JANSSENBIO-017-00040227	JANSSENBIO-017-00040033	JANSSENBIO-017-00047768

JANSSENBIO-017-00047662	JANSSENBIO-017-00047844	JANSSENBIO-017-00047961
JANSSENBIO-017-00035354	JANSSENBIO-017-00035367	JANSSENBIO-017-00035386
JANSSENBIO-017-00035409	JANSSENBIO-017-00035247	JANSSENBIO-017-00035220
JANSSENBIO-017-00035345	JANSSENBIO-017-00035333	JANSSENBIO-017-00035322
JANSSENBIO-017-00035295	JANSSENBIO-017-00045741	JANSSENBIO-017-00045751
JANSSENBIO-017-00045787	JANSSENBIO-021-00002241	JANSSENBIO-021-00002248
JANSSENBIO-021-00002266	JANSSENBIO-021-00002273	JANSSENBIO-021-00002283
JANSSENBIO-021-00002351	JANSSENBIO-021-00002474	JANSSENBIO-021-00002564
JANSSENBIO-021-00002741	JANSSENBIO-021-00003077	JANSSENBIO-021-00003338
JANSSENBIO-021-00003600	JANSSENBIO-021-00003743	JANSSENBIO-021-00003831
JANSSENBIO-021-00003962	JANSSENBIO-030-00005366	JANSSENBIO-031-00006684
JANSSENBIO-032-00000959	JANSSENBIO-032-00000962	JANSSENBIO-031-00005015
JANSSENBIO-032-00000716	JANSSENBIO-031-00005125	JANSSENBIO-030-00003829
JANSSENBIO-030-00007626	JANSSENBIO-030-00006482	JANSSENBIO-030-00006487
JANSSENBIO-031-00005015	JANSSENBIO-032-00000716	JANSSENBIO-031-00005125
JANSSENBIO-030-00003829	JANSSENBIO-030-00007626	JANSSENBIO-030-00006482
JANSSENBIO-030-00006487	JANSSENBIO-031-00002904	JANSSENBIO-031-00013884
JANSSENBIO-031-00013889	JANSSENBIO-031-00013897	JANSSENBIO-030-00004786
JANSSENBIO-030-00004793	JANSSENBIO-030-00004813	JANSSENBIO-030-00004819
JANSSENBIO-031-00012555	JANSSENBIO-031-00008715	JANSSENBIO-031-00011492
JANSSENBIO-030-00009504	JANSSENBIO-031-00002531	JANSSENBIO-031-00002758
JANSSENBIO-032-00000828	JANSSENBIO-030-00005342	JANSSENBIO-030-00005346
JANSSENBIO-031-00004950	JANSSENBIO-032-00000712	JANSSENBIO-030-00003722
JANSSENBIO-030-00003688	JANSSENBIO-031-00005361	JANSSENBIO-030-00004009
JANSSENBIO-030-00004013	JANSSENBIO-030-00004106	JANSSENBIO-030-00004057
JANSSENBIO-031-00015265	JANSSENBIO-031-00000954	JANSSENBIO-030-00000741
JANSSENBIO-030-00000788	JANSSENBIO-032-00000766	JANSSENBIO-031-00006658
JANSSENBIO-031-00002451	JANSSENBIO-031-00002452	JANSSENBIO-031-00002399
JANSSENBIO-031-00002293	JANSSENBIO-031-00002397	JANSSENBIO-031-00002297
JANSSENBIO-031-00005505	JANSSENBIO-030-00004094	JANSSENBIO-031-00005501
JANSSENBIO-030-00004100	JANSSENBIO-030-00004101	JANSSENBIO-031-00007275
JANSSENBIO-030-00005994	JANSSENBIO-030-00005999	JANSSENBIO-030-00006012
JANSSENBIO-030-00009859	JANSSENBIO-031-00011737	JANSSENBIO-030-00009830
JANSSENBIO-031-00003254	JANSSENBIO-031-00003250	JANSSENBIO-032-00000386
JANSSENBIO-032-00000374	JANSSENBIO-032-00000420	JANSSENBIO-030-00002653
JANSSENBIO-031-00012670	JANSSENBIO-031-00012896	JANSSENBIO-031-00012664
JANSSENBIO-031-00012665	JANSSENBIO-031-00012666	JANSSENBIO-031-00012667
JANSSENBIO-031-00012668	JANSSENBIO-030-00001814	JANSSENBIO-031-00001863
JANSSENBIO-031-00001880	JANSSENBIO-030-00001810	JANSSENBIO-030-00000991
JANSSENBIO-030-00000995	JANSSENBIO-032-00000865	JANSSENBIO-030-00005352
JANSSENBIO-031-00006668	JANSSENBIO-031-00001644	JANSSENBIO-031-00001636
JANSSENBIO-031-00001640	JANSSENBIO-030-00001521	JANSSENBIO-030-00001662
JANSSENBIO-030-00003133	JANSSENBIO-030-00003541	JANSSENBIO-031-00005611
JANSSENBIO-031-00005607	JANSSENBIO-030-00004154	JANSSENBIO-030-00004155

JANSSENBIO-030-00005842	JANSSENBIO-030-00005726	JANSSENBIO-030-00005765
JANSSENBIO-031-00006495	JANSSENBIO-031-00006188	JANSSENBIO-030-00004911
JANSSENBIO-031-00006189	JANSSENBIO-031-00006190	

Janssen further responds that the presentations, resources, or programs listed in Amended Interrogatory No. 18 were in use during the time periods listed below based on information presently known to Janssen, including documents contained in custodial files and PRC approval forms. Janssen reserves the right to revise or supplement this information as its investigation and discovery progresses.

- (1) **IV Therapy: An Important Option for Your Patients (Why IV):** December 2012 December 2018.
- (2) Infusion suite layout plan/infusion suite model: Janssen responds that "Infusion Suite Designer"—in use between December 2001 and October 2004—is the only "presentation, resource, or program" that Janssen is presently aware of related to "infusion suite layout plan/infusion suite model."
- (3) **Infusion Optimization Modeler (IOM)**¹: January 2004 February 2014.
- (4) **Efficiency checklist:** February 2004 June 2015.
- (5) **Account Review:** May 2004 June 2007.
- (6) **Managing Biologics in the Physician Office (MBPO):** May 2007 May 2012.²
- (7) **Infusion Services Review³:** January 2013 April 2014.⁴
- (8) **Infusion Business Review (IBiz):** April 2014 June 2019.⁵

¹ In April 2014, Janssen combined the IOM and Infusion Services Review into one new resource, called iBiz.

² The end date for this presentation is the date that records reflect the presentation was last approved by the PRC. As Janssen's PRC Standard Operating Procedures indicate, materials approved by the PRC were required to be rereviewed and approved every 12 months, prior to continued use. *See, e.g.*, JANSSENBIO-018-00001266 at 1270; JANSSENBIO-018-00001292 at 1294; JANSSENBIO-018-00001305 at 1308. Accordingly, the presentation may have been used beyond the last PRC approval date.

³ In April 2014, Janssen combined the IOM and Infusion Services Review into one new resource, called iBiz..

⁴ See supra note 2.

⁵ *Id*.

- (9) **Optimizing patient scheduling and infusion capacity**: Janssen responds that the following "presentations, resources, or programs" relate to "optimizing patient scheduling and infusion capacity":
 - a. **Infusion Suite Scheduling and Staffing:** October 2015 June 2018.
 - b. **Infusion Optimization Modeler (IOM):** January 2004 February 2014.
- (10) **Proactive Practice Management:** February 2008 November 2016.
- (11) **Payer Management:** Janssen responds that "Payer Relationship Management"—in use between July 2015 and June 2017—is the only "presentation, resource, or program" that Janssen is presently aware of related to "payer management."
- (12) **Payer Relationship Management:** July 2015 June 2017.
- (13) **Private Payer Contracting Considerations for Remicade:** April 2002 October 2012.⁸
- (14) **Negotiating Payer Contracts:** Janssen responds that "Private Payer Contracting Considerations for Remicade"—in use between April 2002 and October 2012—is the only "presentation, resource, or program" that Janssen is presently aware of related to "negotiating payer contracts."
- (15) Contracting, acquiring drug, and managing payers: Janssen responds that "Private Payer Contracting Considerations for Remicade"—in use between April 2002 and October 2012—is the only "presentation, resource, or program" that Janssen is presently aware of related to "negotiating payer contracts."
- (16) Raising the Infusion Suite Experience (RISE): February 2013 June 2020.9
- (17) Enhancing quality measures, patient experience, and satisfaction: Janssen responds that he following "presentations, resources, or programs" relate to "enhancing quality measures, patient, experience, and satisfaction":
 - a. **Raising the Infusion Suite Experience (RISE):** February 2013 June 2020. 10

⁶ *Id*.

⁷ *Id*.

⁸ *Id*.

⁹ *Id*.

¹⁰ *Id*.

- b. Enhancing Infusion Efficiency: April 2010 November 2011. 11
- (18) **Protocols and Standard Operating Procedures:** Janssen responds that "Considerations for SOPs in the Infusion Suite"—in use between September 2015 and November 2016—is the only "presentation, resource, or program" that Janssen is presently aware of related to "Protocols and Standard Operating Procedures."
- (19) Optimizing your prior authorization/benefit investigations workflows:
 Janssen responds that "Reimbursement Principles for Successful Practices"—in
 use between July 2008 and January 2013— is the only "presentation, resource, or
 program" that Janssen is presently aware of related to "Optimizing your prior
 authorization/benefit investigations workflows."
- (20) Utilizing alternative approaches to mitigate risk with buy-and-bill: Janssen is not aware of any "presentation, resource, or program" regarding "utilizing alternative approaches to mitigate risk with buy-and-bill." Further, this "presentation, resource, or program" is not identified in Relator's Supplemental Response to Janssen's Interrogatory No. 2 (May 23, 2022).
- (21) Instituting best practice standard operating procedures (SOPs) and clinical protocols: Janssen responds that "Considerations for SOPs in the Infusion Suite"—in use between September 2015 and November 2016—is the only "presentation, resource, or program" that Janssen is presently aware of related to "instituting best practice standard operating procedures (SOPs) and clinical protocols."
- (22) **Preparing the total office for ICD-10:** October 2010 December 2021. 12
- (23) Electronic Medical Records and Meaningful Use: April 2014 June 2016.
- (24) Achieving Meaningful Use 2 with electronic health records: Janssen responds that "Electronic Medical Records and Meaningful Use"—in use between April 2014 and June 2016—is the only "presentation, resource, or program" that Janssen is presently aware of related to "Achieving Meaningful Use 2 with electronic health records."
- (25) **Vial Trend Update:** Janssen is not aware of any "presentation, resource, or program" regarding "Vial Trend Update." Further, this "presentation, resource, or program" is not identified in Relator's Supplemental Response to Janssen's Interrogatory No. 2 (May 23, 2022).
- (26) Controlling and managing the infusible inventory: Janssen is not aware of any "presentation, resource, or program" regarding "Controlling and managing the

¹¹ *Id*.

¹² *Id*.

- infusible inventory." Further, this "presentation, resource, or program" is not identified in Relator's Supplemental Response to Janssen's Interrogatory No. 2 (May 23, 2022).
- (27) **Inventory and Supply Management:** September 2015 May 2020. ¹³
- (28) **Infusion Referrals: Improving the Continuity of Care:** April 2014 July 2020. ¹⁴
- (29) Enhancing the continuity of care with inbound and/or outbound referrals: Janssen responds that "Infusion Referrals: Improving the Continuity of Care"—in use between April 2014 and July 2020—is the only "presentation, resource, or program" that Janssen is presently aware of related to "enhancing the continuity of care with inbound and/or outbound referral."
- (30) Ambulatory Surgical Centers and Infusion Services: July 2003 April 2015.
- (31) Successful Infusion Suite Management: October 2010 May 2012. ¹⁵ Janssen further responds that "Successful Implementation of a New Infusion Suite" was in use between April 2010 and May 2012 ¹⁶; "Successful Infusion Suite Management for Gastroenterology" was in use between January 2011 and May 2012 ¹⁷; and "Successful Implementation of a New Infusion Suite for Gastroenterology Practices" was in use between October 2010 and May 2012. ¹⁸

¹³ *Id*.

¹⁴ *Id*.

¹⁵ *Id*.

¹⁶ *Id*.

¹⁷ *Id*.

¹⁸ *Id*.

VERIFICATION

I am the Vice President, Immunology Portfolio Strategy at Janssen Biotech, Inc. I am authorized to make this verification on behalf of Janssen Biotech, Inc. I have read Defendant's foregoing responses to Plaintiff-Relator Julie Long's Interrogatory No. 3, and Amended Interrogatory Nos. 8 and 18 and know their contents. I am informed and believe that the matters stated therein are true and on that ground certify or declare under penalty of perjury that the same are true and correct.

Executed on October 7, 2022.

Brian Smith

AS TO OBJECTIONS AND RESPONSES:

Dated: October 7, 2022 Ethan M. Posner

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document has been served by electronic mail on October 7, 2022, to the following counsel of record:

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